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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/759,374	01/16/2004	Dean G. Hafeman	THI-003	6709
51414	7590	02/28/2006	EXAMINER	
GOODWIN PROCTER LLP PATENT ADMINISTRATOR EXCHANGE PLACE BOSTON, MA 02109-2881			GOUGH, TIFFANY MAUREEN	
			ART UNIT	PAPER NUMBER
			1651	
DATE MAILED: 02/28/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/759,374

Applicant(s)

HAFEMAN, DEAN G.

Examiner

Tiffany M. Gough

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-35 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-8, drawn to a method for maintaining cell viability in a microfluidic device, classified in class 435, multiple subclasses including 325,374,410,420, and 431.
- II. Claims 9-14, drawn to a method for loading cells into a microfluidic device, classified in class 435, subclass 374
- III. Claims 15-28 drawn to a microfluidic device for maintaining viability of a cell, classified in class 435, multiple subclasses including 288.2, 288.3,288.4,288.5, and 286.5.
- IV. Claims 29-31, drawn to a microfluidic device for retaining a cell sample including a plurality of cells, classified in class 435, subclass 288.3
- V. Claims 32-35, drawn to a system for monitoring an activity of a cell, classified in class 435 and 250 numerous subclasses including 287.1,288.5,286.5,286.1,286.2,288.3 and 458.1

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation and functions

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and also have different effects. Group I recites a method for maintaining cell viability, whereas Group II recites a method for loading cells into a device. Thus, the two groups are clearly unrelated in that they require different method steps, have different functions requiring different embodiments, and thus different effects on the inventions as claimed. Given the numerous embodiments recited by both groups, extensive searching in numerous subclasses would be required and would therefore place significant burden on the examination process.

Inventions I and III are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus as claimed can be used to practice another and different process. It is well-known in the art that microfluidic devices, such as a microphysiometer and/or a cytosensor has many different uses in cell biology. One could use such a device to monitor cellular responses to an array of chemical substances such as ligands for plasma membrane receptors by measuring proton excretions, to detect specific molecules, to understand cellular metabolic pathway changes in response to stimulants, investigate cell function and biochemistry, to distinguish between aerobic and anaerobic pathways, and one may also be able to access the toxicity of environmental pollutants using such a device.

Inventions I and IV and II and IV are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as

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claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus could be used to receive a sample other than a cell sample, such as a noncellular composition containing beads coated with an enzyme and further separated according to size, blood samples, protein or antibody solutions and various buffers. The device as claimed could also be used, as stated above, to access the toxicity of environmental pollutants.

Inventions I and V are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus as claimed can be used to practice another and different process. Applicant discloses using the apparatus for maintaining viability of a cell and for monitoring activity of a cell. These processes have different functions and steps. To “maintain” viability of a cell, one would not necessarily have to practice the steps necessary in monitoring any specific activity of a cell. One could be monitoring, as stated above, cellular responses to an array of chemical substances such as ligands for plasma membrane receptors by measuring proton excretions, to detect specific molecules, to understand cellular metabolic pathway changes in response to stimulants, investigate cell function and biochemistry, and/or distinguish between aerobic and anaerobic pathways. Monitoring such pathways would different steps, tools, and products than would “maintaining” cell viability.

Inventions II and III and II and V are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the process of loading cells into a device could be used to load other products such as environmental agents used in toxicity test, blood samples, protein or antibody solutions and buffers.

Inventions III and IV and III and V are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, invention III has separate utility such as, the device as claimed comprising: a cell duct plate, membrane , and a flow channel plate, is used to maintain viability of a cell. Invention IV, essentially the plate of the microfluidic device, has the separate utility of retaining cells. See MPEP § 806.05(d). Invention V is disclosed as a system for monitoring an activity of a cell comprising: a cell plate, a membrane, a flow channel plate, a pump, a controller and a sensor. Invention V encompasses additional embodiments, which enables the invention to further detect and monitor cellular activities.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed invention:

- (a) the porous membrane materials recited in claims 4 and 18

If applicant elects Group I or III, as set forth above, applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 4 and 18 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over

the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tiffany M. Gough whose telephone number is 571-272-0697. The examiner can normally be reached on M-F 8-5 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



FRANCISCO PRATS
PRIMARY EXAMINER